

WHAT IS CLAIMED IS:

1. A composition comprising (a) a pharmaceutically acceptable carrier, diluent, and/or excipient, (b) a tissue factor antagonist, and (c) protein C or a protein C-related polypeptide.
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2. The composition of claim 1, wherein the TF antagonist is a factor VII polypeptide that has a substantially reduced ability to catalyze factor X to factor Xa as compared to factor VII.
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3. The composition of claim 2, wherein the TF antagonist is a factor VII polypeptide catalytically inactivated in the active site.
4. The composition of claim 3, wherein the TF antagonist is wild-type human factor VII catalytically inactivated in the active site.
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5. The composition of claim 3, wherein the factor VII polypeptide is catalytically inactivated in the active site with a chloromethyl ketone inhibitor independently selected from the group consisting of Phe-Phe-Arg chloromethyl ketone, Phe-Phe-Arg chloromethylketone, D-Phe-Phe-Arg chloromethyl ketone, D-Phe-Phe-Arg chloromethylketone, Phe-Pro-Arg chloromethylketone, D-Phe-Pro-Arg chloromethylketone, Phe-Pro-Arg chloromethylketone, D-Phe-Pro-Arg chloromethylketone, L-Glu-Gly-Arg chloromethylketone and D-Glu-Gly-Arg chloromethylketone, Dansyl-Phe-Phe-Arg chloromethyl ketone, Dansyl-Phe-Phe-Arg chloromethylketone, Dansyl-D-Phe-Phe-Arg chloromethyl ketone, Dansyl-D-Phe-Phe-Arg chloromethylketone, Dansyl-Phe-Pro-Arg chloromethylketone, Dansyl-D-Phe-Pro-Arg chloromethylketone, Dansyl-Phe-Pro-Arg chloromethylketone, Dansyl-D-Phe-Pro-Arg chloromethylketone, Dansyl-L-Glu-Gly-Arg chloromethylketone, and Dansyl-D-Glu-Gly-Arg chloromethylketone.
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6. The composition of claim 4, wherein the factor VII polypeptide is catalytically inactivated in the active site with a chloromethyl ketone inhibitor independently selected from the group consisting of Phe-Phe-Arg chloromethyl ketone, Phe-Phe-Arg chloromethylketone, D-Phe-Phe-Arg chloromethyl ketone, D-Phe-Phe-Arg chloromethylketone, Phe-Pro-Arg chloromethylketone, D-Phe-Pro-Arg chloromethylketone, Phe-Pro-Arg chloromethylketone, D-Phe-Pro-Arg chloromethylketone, L-Glu-Gly-Arg chloromethylketone and D-Glu-Gly-Arg chloromethylketone, Dansyl-Phe-Phe-Arg chloromethyl ketone, Dansyl-Phe-Phe-Arg chloromethylketone, Dansyl-D-Phe-Phe-Arg chloromethyl ketone, Dansyl-D-Phe-Phe-Arg
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chloromethylketone, Dansyl-Phe-Pro-Arg chloromethylketone, Dansyl-D-Phe-Pro-Arg chloromethylketone, Dansyl-Phe-Pro-Arg chloromethylketone, Dansyl-D-Phe-Pro-Arg chloromethylketone, Dansyl-L-Glu-Gly-Arg chloromethylketone, and Dansyl-D-Glu-Gly-Arg chloromethylketone.

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7. The composition of claim 1, wherein the TF antagonist is an antibody against TF.

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8. The composition of claim 7, wherein the TF antagonist is a fully human monoclonal antibody or a humanized antibody.

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9. The composition of claim 7, wherein the TF antagonist is a Fab fragment; a monovalent fragment consisting of the VL, VH, CL and CH I domains; a F(ab)₂ fragment; a F(ab')₂ fragment; a bivalent fragment comprising two Fab fragments linked by a disulfide bridge at the hinge region; a Fd fragment consisting essentially of the VH and CH1 domains; a Fv fragment consisting essentially of the VL and VH domains of a single arm of an antibody; a dAb fragment; an isolated complementarity determining region (CDR); a single chain Fv (scFv); or a combination of any thereof.

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10. The composition of claim 1, wherein the protein C or protein C-related polypeptide is human protein C.

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11. The composition of claim 3, wherein the protein C or protein C-related polypeptide is human protein C.

12. The composition of claim 7, wherein the protein C or protein C-related polypeptide is human protein C.

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13. The composition of claim 10, wherein the protein C is activated human protein C.

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14. The composition of claim 1, wherein the composition comprises a protein C-related polypeptide comprising an amino acid sequence that is at least about 80% identical to the amino acid sequence of human protein C and the ratio of activity of the protein C-related polypeptide to human plasma protein C is at least about 1.25.

15. The composition of claim 1, wherein the TF antagonist and the protein C or protein C-related polypeptide are present in a mass ratio of between about 100:1 and about 1:100.

5 16. A method of inducing, promoting, and/or enhancing at least one physiological response associated with the prevention or treatment of a thrombotic disease, coagulopathic disease, respiratory disease, or inflammatory disease associated with TF in a subject suffering from or at risk of acquiring such a disease comprising administering a TF antagonist and a protein C or a protein C-related polypeptide to the subject in an amount sufficient to detectably
10 induce, promote, and/or enhance the physiological response.

17. The method of claim 16, wherein the TF antagonist and the protein C or protein C-related polypeptide are administered in single-dosage form.

15 18. The method of claim 16, wherein the TF antagonist is administered to the subject in a first dosage form and the protein C or a protein C-related polypeptide is administered to the patient in a second dosage form.

20 19. The method of claim 16, wherein the subject is suffering from or at risk of developing systemic inflammatory response syndrome, acute lung injury, acute respiratory distress syndrome, disseminated intravascular coagulation, sepsis, any combination thereof, or multiple organ failure in association with any of the preceding syndromes.

25 20. The method of claim 20, wherein the method comprises administering the TF antagonist and protein C or protein C-related polypeptide by injection.